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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/852,519
Filing Date: May 10, 2001
Appellant(s): GILLESPIE, DONALD E.

MAILED
AUG 4 2004
GROUP

John Posa
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 13, 2004.

(1) *Real Party in Interest*

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A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed herewith to amend claim 8 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because claim 8 should stand or fall with claims 5-7, because it does not add any elemental limitation to the punctuam plug of claim 5.

Examiner agrees with appellant's statement with respect to Group I.

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(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,300,020	L'Esperance, Jr	4-1994
4,959,048	Sedar et al	4,959,048
3,949,750	Freeman	10-1974
5,178,635	Gwon et al	1-1993

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by
L'Esperance US Patent 5,300,020.

L'Esperance discloses an implantable device for controlling drainage flow of aqueous fluid from the anterior chamber of the eye. (abstract). Accordingly, such device of L'Esperance meets the limitations of the instant punctum plug. The device of L'Esperance contains an outwardly exposed surface (see figure 1, element # 17; col 2, lines 55-65). L'Esperance further teaches that his plug contains an energy-absorbing

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compound such as fluorescein, Indocyanine green, methylene blue or Rose Bengal at the tubular section of the plug. Accordingly, L'Esperance anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seder et al US Patent 4,959,048 or Freeman US Patent 3,949,750 in view of Gwon et al US Patent 5,178,635.

Claims 1-8 are directed to ophthalmic plugs comprising a substance that causes the plug to be more easily visualized.

Seder and Freeman both teach punctual plugs that are flexible and suitable in dimension and of material to be inserted into punctual apertures. The plugs of both Freeman and Seder have an outwardly exposed surface (see abstracts, figures).

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Seder's and Freeman's plugs do not have a substance that can cause the plug to be more easily visualized.

Gwon is merely used to show that suitable dyes and fluorescent tracers have been used in the art as a means for improving visualization in ophthalmic devices. (col 5, lines 30-50). Gwon explicitly teaches that a tracer may be incorporated into the insert by physical admixture or dissolution into the implant matrix. (col 5, lines 47-50). Such tracer is able to illuminate with light at its own illumination wavelength (as required by the instant claims 5-7). Accordingly, using a tracer in the matrix of an ophthalmic device is a general knowledge available in the art.

Thus, even though neither Seder nor Freeman teach a tracer in their plug, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a tracer such as florescence into the matrix of Seder's or Freeman's plugs, because as taught by Gwon, the ordinary artisan would have had a reasonable expectation of success in improving the visualization of the plug in the recipient's eyes.

(11) *Response to Argument*

Appellant's arguments have been fully considered but are not found persuasive.

A. Claims 1-4, 6 should stand rejected under 35 U.S.C. 102(b) as being anticipated by L'Esperance US Patent 5,300,020, because L'Esperance meets all elemental limitations of the instant claims.

Appellant argues that that Examiner misinterprets the L'Esperance Reference. Appellant then adds that even though L'Esperance reference teaches the use of photon, heat or other energy absorbing compound, it is for the purpose of adjusting fluid flow and not for visualization.

In response Examiner states a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Here, L'Esperance teaches that his plug contains an energy-absorbing compound such as fluorescein or Rose Bengal at the tubular section of the plug. Accordingly, L'Esperance provides the same elements as the instant plug regardless of its intended use. Thus, the rejection should be maintained because L'Esperance anticipates all elemental limitations of the instant claims.

B. Claims 1-8 should stand rejected under 35 U.S.C. 103(a) as being unpatentable over Seder et al US Patent 4,959,048 or Freeman US Patent 3,949,750 in view of Gwon et al US Patent 5,178,635, because all elements of the instant limitations are described by the combined teachings of the references and said teachings provide a reasonable expectation of success consistent with the reasoning set forth in *Graham v. John Deere*. 383 U.S. 1, 148 USPQ 459 (1966).

First, in response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the combined teachings of references provide for all the limitations of the instant claims.

Second, Appellant argues that there is no teachings or suggestion from the prior art to support the Examiner's position. In response, Examiner states that Gwon explicitly

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teaches that a tracer such as fluorescent tracer provides means for enabling visual indication of an ophthalmic device and that such tracer may be incorporated into the insert by physical admixture or dissolution into the implant matrix. (col 5, lines 35-36, 47-50). Examiner construes such statements by Gwon as an indication that suitable dyes and fluorescent tracers have been used in the art as a means for improving visualization in ophthalmic devices. (col 5, lines 30-50). Further, Appellant appears to be ignoring the general knowledge in the art that such tracers are able to illuminate with light at its own illumination wavelength. Thus, there is ample suggestion in the art to support Examiner's position.

In the instant case Seder and Freeman both teach punctual plugs that are flexible and suitable in dimension and of material to be inserted into punctual apertures. Gwon shows suitable dyes and fluorescent tracers have been used in the art as a means for improving visualization in ophthalmic devices. (col 5, lines 30-50). Gwon explicitly teaches that a tracer may be incorporated into the insert by physical admixture or dissolution into the implant matrix. (col 5, lines 47-50). Seder's and Freeman's punctual plugs are ophthalmic devices.

Accordingly, using a tracer, such as those taught by Gwon, in the matrix of an ophthalmic device, such as those taught by Seder and Freeman, is a general knowledge available in the art. Thus, even though neither Seder nor Freeman teach a tracer in their plug, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a tracer such as fluorescence into the matrix of Seder's or Freeman's plugs, because as taught by Gwon, the ordinary artisan would have had a

reasonable expectation of success in improving the visualization of the plug in the recipient's eyes.

Appellant argues that there is no factual basis to support Examiner's conclusion of obviousness. However, it is well settled in Patent Law that "[F]or obviousness under §103, all that is required is a reasonable expectation of success." *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). Here, the information in the Seder and Freeman references, when combined with the Gwon reference provided such a reasonable expectation of success.

Examiner has previously set forth in the record that "[O]bviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious." *In re Merck & Co .*, 800 F.2d at 1098, 231 USPQ at 380; *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co .*, 730 F.2d 1452, 1461, 221 USPQ 481, 488 (Fed. Cir. 1984); *In re Papesch*, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963). Appellant has not provided any evidence showing nonobviousness or provide any unexpected results. Accordingly, for the reasons of record the rejection is hereby maintained.

Appellant then argues that claim 5 adds to claim 1 the limitation of a punctuam plug which is illuminated with light at an illumination wavelength. Appellants adds that

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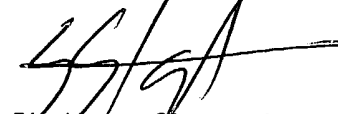
claim 8 adds to claim 5 the limitation of the radiated light being outside the visible spectrum and further including a detector for detecting the radiated light.

In response, Examiner states that claim 5 merely adds a functional limitation to claim 1 punctum plug. Respectively, claim 8, which depends on claim 5, fails to add any elemental limitation to the punctum plug of claim 1, because it describes a detector independent in function from the components of claimed punctum plug. Moreover, the scope for such limitation encompasses the use of the naked eye of a second person as the detector of radiating light from the punctum plug. Specification at page 3, lines 5-7 describes that the optical element may be viewed "by a second person." Then at page 4, lines 16-20, the specification describes that the claimed invention encompass visualization with "an unaided eye."

The cited references teach such limitation. Both Seder and Freeman provide the application of their punctum plug by a second person. Such teaching is within the scope of claim 8. Nevertheless, assuming *arguendo* that claim 5-8 add additional limitations to claim 1 punctum plug, the combined teachings of the references still provide for the use of a illuminating light and a detector from an external source, because Gwon specifically recites the application of a UV illuminator and a detector to visualize his tracers or dyes (see col 7, lines 10-19; col 8, lines 27-40). Therefore, the limitations of the instant claims are described by the combined teaching of the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

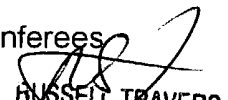


Shahnaz Sharareh

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July 19, 2004

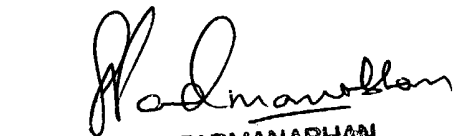
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